

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended). An apparatus for delivering a biologically active material to a body lumen comprising:
  - a catheter having a distal portion and a proximal portion;
  - a balloon, having an outer surface, disposed at the distal portion of the catheter; and
  - a plurality of micro-needles disposed upon the outer surface of the balloon, ~~wherein the micro-needles are capable of contacting the body lumen~~ to deliver the biologically active material to the body lumen, ~~and wherein the micro-needles are capable of being ruptured; and~~ said the balloon has an having a first interior compartment for containing the biologically active material and a second compartment, without fluid communication with the first compartment, for receiving an inflation material to inflate the balloon.
2. (Currently Amended). The apparatus of claim 1, wherein ~~said catheter has a first lumen therethrough; said interior compartment is in fluid communication with the first lumen; and each micro-needle of said plurality of~~ micro-needles ~~each have~~ has a lumen in fluid communication with the ~~interior~~ first compartment of the balloon to allow the biologically active material to be delivered through the ~~lumens~~ lumen of the ~~micro-needles~~ micro-needle to the body lumen.
3. (Currently Amended). The apparatus of claim 1 ~~2~~, wherein the catheter comprises a the first lumen in communication with the first compartment of the balloon of the catheter is used for both inflating the balloon and delivering the biologically active material to the first compartment.

4. (Currently Amended). The apparatus of claim 3 2, wherein the ~~first lumen is used for delivering the biologically active material, and said catheter further comprises~~ has a second lumen in communication with the second compartment of the balloon for inflating the balloon.

5. (Canceled).

6. (Withdrawn). The apparatus of claim 4, wherein said catheter has a third lumen in fluid communication with the interior compartment for delivering a second biologically active material.

7. (Withdrawn). The apparatus of claim 6, wherein the catheter has a fourth lumen for blood perfusion.

8. (Canceled).

9. (Currently Amended). The apparatus of claim 1, wherein ~~the~~ each micro-needle of the plurality micro-needles has ~~micro-needles have~~ a diameter between about 10 nm and about 100  $\mu\text{m}$ .

10. (Currently Amended). The apparatus of claim 1, wherein ~~the micro-needles have~~ each micro-needle of said plurality of micro-needles has a length between about 1  $\mu\text{m}$  and about 1 mm.

11. (Original). The apparatus of claim 10, wherein the length is between about 10  $\mu\text{m}$  and about 500  $\mu\text{m}$ .

12. (Original). The apparatus of claim 11, wherein the length is between about 30  $\mu\text{m}$  and about 200  $\mu\text{m}$ .

13. (Original). The apparatus of claim 1, wherein there are more than about ten (10) micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

14. (Original). The apparatus of claim 13, wherein there are between about  $1 \times 10^2$  and about  $1 \times 10^6$  micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

15. (Currently Amended). An apparatus for delivering a biologically active material to a body lumen, comprising:

a catheter having a distal portion and a proximal portion;

a balloon, having an outer surface and containing the biologically active material,

disposed at the distal portion of the catheter; and

a plurality of sealed and rupturable micro-needles disposed upon the outer surface of the balloon, each micro-needle having at least one weak spot that breaks upon triggering to generate at least one opening to deliver the biologically active material from the balloon through the openings of the micro-needles to the body lumen.

~~wherein the micro-needles are capable of contacting the body lumen to deliver the biologically active material to the body lumen, wherein the balloon has an interior compartment for containing the biologically active material, wherein the micro-needles each have a lumen in fluid communication with the interior compartment, and said micro-needles allow the biologically active material to be delivered from the interior compartment through the lumens of the micro-needles to the body lumen.~~

16. (Withdrawn). The apparatus of claim 15, wherein a second biologically active material is coated onto the outer surface of the balloon.

17. (Currently Amended). The apparatus of claim 15 wherein the catheter has a first lumen ~~therethrough~~; and the balloon comprises a wherein the interior compartment containing the biologically active material and is in fluid communication with the first lumen.

18. (Currently Amended). The apparatus of claim 15, wherein the balloon comprises outer surface of the balloon is part of a balloon wall defining the outer surface and ~~wherein the catheter has a first lumen therethrough; and wherein the interior compartment is in fluid communication with the first lumen, and said the~~ balloon wall contains defines a plurality of pores whereby the biologically active material is delivered to the body lumen through the pores.

19. (Currently Amended). The apparatus of claim 18 wherein the balloon wall comprises an inner layer and an outer layer, and wherein said plurality of pores are ~~located~~ defined in the outer layer.

20. (Withdrawn). The apparatus of claim 19 wherein biologically active material is located between the inner layer and the outer layer.

21. (Currently Amended). The apparatus of claim 15, wherein ~~the~~ each micro-needle has ~~micro-needles have~~ a diameter between about 10 nm and about 100  $\mu$ m.

22. (Currently Amended). The apparatus of claim 15, wherein each micro-needle has ~~the micro-needles have~~ a length between about 1  $\mu$ m and about 1 mm.

23. (Original). The apparatus of claim 22, wherein the length is between about 10  $\mu\text{m}$  and about 500  $\mu\text{m}$ .

24. (Original). The apparatus of claim 23, wherein the length is between about 30  $\mu\text{m}$  and about 200  $\mu\text{m}$ .

25. (Original). The apparatus of claim 15, wherein there are more than about ten (10) micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

26. (Original). The apparatus of claim 25, wherein there are between about  $1 \times 10^2$  and about  $1 \times 10^6$  micro-needles per  $\text{cm}^2$  of the outer surface of the balloon upon which the micro-needles are disposed.

27. (Currently Amended). An apparatus for delivering a biologically active material to a body lumen comprising:

a catheter having a distal portion and a proximal portion;

a balloon, having a balloon wall including a layer defining an outer surface and an inner surface, disposed at the distal portion of the catheter; and

a plurality of micro-needles disposed upon the outer surface of the balloon, wherein the micro-needles are capable of contacting the body lumen to deliver the biologically active material to the body lumen; ~~the outer surface of the balloon is part of a balloon wall;~~ and the micro-needles are disposed upon a plate, which is attached to the inner surface of the layer of said balloon wall in a manner such that the micro-needles project through the layer of the balloon wall.

28. (Currently Amended). The apparatus of claim 27, wherein the plate is attached to the balloon in a manner such that the micro-needles are capable of being retracted when the balloon is deflated and capable of being projected through the balloon wall when the balloon is expanded.

29. (Currently Amended) An apparatus for delivering a biologically active material to a body lumen comprising:

(a) a catheter having a distal portion, a proximal portion and a first lumen therethrough;

(b) a balloon disposed at the distal portion of the catheter, wherein the balloon has an interior compartment in fluid communication with the first lumen of the catheter; the balloon has an outer surface having a plurality of micro-needles disposed thereon; and each micro-needle of said plurality of micro-needles has have a lumen in fluid communication with the interior compartment and wherein the micro-needles are capable of being ruptured; and

(c) a triggering source, ~~wherein the triggering source ruptures to rupture~~ the micro-needles when activated to deliver the biologically active material from the interior compartment of the balloon through the micro-needle lumens to the body lumen, wherein the triggering source is selected from the group consisting of a shockwave, ultrasound energy and energy source for delivering a detachable coil.

30. (Original). The apparatus of claim 29, wherein the balloon outer surface is part of a balloon wall, and the micro-needles are disposed upon a plate attached to the balloon wall in a manner such that the micro-needles project through the balloon wall.

31. (Original). The apparatus of claim 29, wherein the triggering source is disposed at the proximal portion of the catheter.

32. (Canceled).

33. (Previously Presented). The apparatus of claim 29, wherein the triggering source is a shockwave.

34. (Canceled).

35. (New) The apparatus of claim 27, wherein the plate is solid.

36. (New) The apparatus of claim 27, wherein the plate is porous.

37. (New) The apparatus of claim 27, wherein the balloon wall also includes an additional layer and the plate is between the layer and the additional layer.

38. (New) The apparatus of claim 27, wherein the biologically active material is contained in the layer of the balloon wall.

39. (New) The apparatus of claim 27, wherein the balloon includes a first compartment for storing the biologically active material and a second compartment for inflating the balloon.